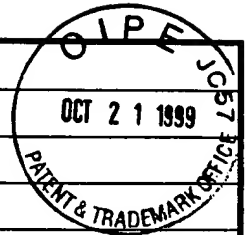


# TRANSMITTAL FORM

|                           |                     |
|---------------------------|---------------------|
| Application Serial Number | 09/248,964          |
| Filing Date               | February 12, 1999   |
| First Named Inventor      | Wucherpennig et al. |
| Group Art Unit            | 1646                |
| Examiner Name             | Not yet assigned    |
| Attorney Docket No.       | HAR-005             |



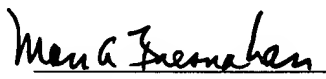
## ENCLOSURES (check all that apply)

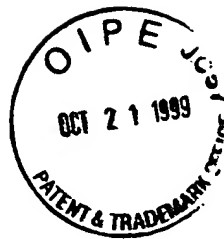
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| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Check Attached<br><input type="checkbox"/> Copy of Fee Transmittal Form<br><br><input type="checkbox"/> Amendment/Response<br><br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]<br><br><input type="checkbox"/> Extension of Time Request<br><br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input checked="" type="checkbox"/> Form PTO-1449<br><input checked="" type="checkbox"/> Copies of IDS Citations A1-A9, B1-B-9, C1-C77<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><br><input type="checkbox"/> Response to Missing Parts/ Incomplete Application | <input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553)<br><br><input type="checkbox"/> Formal Drawing(s)<br><br><input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition to Convert to a Provisional Application<br><br><input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)<br><br><input type="checkbox"/> Terminal Disclaimer<br><br><input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application<br><br><input type="checkbox"/> Small Entity Statement<br><br><input type="checkbox"/> Request for Refund<br><br><input type="checkbox"/> After Allowance Communication to Group | <input type="checkbox"/> Appeal Communication to Board of Patent Appeals and Interferences<br><br><input type="checkbox"/> Appeal Communication to Group ( <i>Appeal Notice, Brief, Reply Brief</i> )<br><br><input type="checkbox"/> Status Letter<br><br><input checked="" type="checkbox"/> Return Receipt Postcard<br><input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8<br><br><input type="checkbox"/> Additional Enclosure(s) ( <i>please identify below</i> ) |
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### CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator  
 Testa, Hurwitz & Thibeault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110  
 Tel. No.: (617) 248-7000  
 Fax No.: (617) 248-7100

### SIGNATURE BLOCK

Respectfully submitted,  
  
 Maureen A. Bresnahan  
 Attorney for Applicants  
 Testa, Hurwitz & Thibeault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110  
  
 Date: October 14, 1999  
 Reg. No. P-44,559  
 Tel. No.: (617) 248-7103  
 Fax No.: (617) 248-7100



GP 1646  
PATENT  
Attorney Docket No. HAR-005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Wucherpennig et al.

SERIAL NO.: 09/248,964

GROUP NO.:

1646

FILING DATE: February 12, 1999

EXAMINER:

Not yet assigned

TITLE:

MONOVALENT, MULTIVALENT, AND MULTIMERIC MHC  
BINDING DOMAIN FUSION PROTEINS AND CONJUGATES,  
AND USES THEREFOR

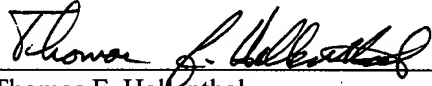
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CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on this 14<sup>th</sup> day of October, 1999.

  
Thomas F. Hellenthal

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith is/are:

Transmittal Form (1 pg.); Information Disclosure Statement (2 pgs.); PTO Form 1449 (7 pgs.); copies of references cited A1-A9, B1-B9, and C1-C77; and a return postcard.

BRESNAHA6615/8.A842071-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Wucherpennig et al.  
SERIAL NO.: 09/248,964 GROUP NO.: 1646  
FILING DATE: February 12, 1999 EXAMINER: Not yet assigned  
TITLE: MONOVALENT, MULTIVALENT, AND MULTIMERIC MHC  
BINDING DOMAIN FUSION PROTEINS AND CONJUGATES,  
AND USES THEREFOR



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. §1.97, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the references are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **Filing Date** or before the mailing date of the **First Office Action** on the merits; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under Rule 1.17(p), namely **\$240.00**, is included herein, or
- ☐ (3) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, **AND**
- ☐ Applicant hereby Petitions the Commissioner to accept and consider the attached Information Disclosure Statement, **AND**



- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee due under Rule 1.17(i)(I), namely **\$130.00** is included herein.

It is respectfully requested that each of the references shown on the attached Form PTO-1449 be made of record in this application.

#### **STATEMENT**

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

- ☐ 1. [E]ach item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application **not more than** three months prior to the filing date of the Information Disclosure Statement; or
- ☐ 2. [N]o item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any** individual designated in §1.56(c) **more than** three months prior to the filing of the Information Disclosure Statement.

#### **FEE AUTHORIZATION**

Should any fee associated with the submission of this paper not be attached hereto as a check, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 20-0531. Any overpayments should be credited to said Deposit Account.

Respectfully submitted,

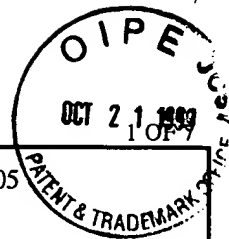
  
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Maureen A Bresnahan  
Attorney for Applicants  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110

Date: October 14, 1999  
Reg. No. P-44,559

Tel. No.: (617) 248-7103  
Fax No.: (617) 248-7100

BRESNAHA6615/8.842028



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| <b>FORM PTO - 1449</b><br><br><b>INFORMATION DISCLOSURE STATEMENT</b> | <b>ATTORNEY DOCKET NO.:</b> HAR-005<br><br><b>APPLICANT(S):</b> Wucherpennig et al.<br><br><b>SERIAL NO.:</b> 09/248,964<br><br><b>FILING DATE:</b> February 12, 1999 <b>GROUP:</b> 1646 |
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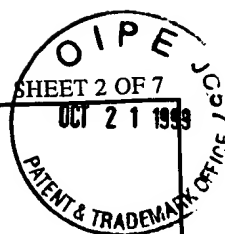
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| <b>U.S. PATENT DOCUMENTS</b> |
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| EXAM.<br>INIT. |    | DOCUMENT<br>NUMBER | DATE     | NAME                   | CLASS | SUB<br>CLASS | FILING DATE IF<br>APPROPRIATE |
|----------------|----|--------------------|----------|------------------------|-------|--------------|-------------------------------|
|                | A1 | 5,928,647          | 07/27/99 | Rock                   | 424   | 196.11       | 01/10/94                      |
|                | A2 | 5,820,866          | 10/13/98 | Kappler et al.         | 424   | 192.1        | 03/04/94                      |
|                | A3 | 5,714,166          | 02/03/98 | Tomalia <i>et al.</i>  | 424   | 486          | 03/07/95                      |
|                | A4 | 5,541,087          | 07/30/96 | Lo et al.              | 435   | 697          | 09/14/94                      |
|                | A5 | 5,338,532          | 08/16/94 | Tomalia <i>et al.</i>  | 424   | 1.49         | 02/13/91                      |
|                | A6 | 5,314,813          | 05/24/94 | Peterson <i>et al.</i> | 435   | 172.3        | 02/19/92                      |
|                | A7 | 5,284,935          | 02/08/94 | Clark <i>et al.</i>    | 530   | 403          | 12/28/90                      |
|                | A8 | 5,260,422          | 11/09/93 | Clark <i>et al.</i>    | 530   | 403          | 04/23/91                      |
|                | A9 | 5,130,297          | 07/14/92 | Sharma <i>et al.</i>   | 514   | 8            | 08/30/90                      |

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| <b>FOREIGN PATENT DOCUMENTS</b> |
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| EXAM. INIT. | DOCUMENT NUMBER | DATE         | COUNTRY CODE | CLASS | SUB CLASS | FILING DATE | ABSTRACT ONLY | ENGLISH LANG Y/N |
|-------------|-----------------|--------------|--------------|-------|-----------|-------------|---------------|------------------|
|             | B1              | WO 99/09064  | 02/25/99     | PCT   |           | 11/04/97    |               | Y                |
|             | B2              | WO 98/06749  | 02/19/98     | PCT   |           | 08/15/97    |               | Y                |
|             | B3              | WO 98/03552  | 01/29/98     | PCT   |           | 07/15/97    |               | Y                |
|             | B4              | WO 97/44667  | 11/27/97     | PCT   |           | 05/21/97    |               |                  |
|             | B5              | WO 97/35991  | 10/02/97     | PCT   |           | 03/28/97    |               | Y                |
|             | B6              | WO 96/04314  | 02/15/96     | PCT   |           | 07/31/95    |               | Y                |
|             | B7              | WO 94/15635  | 07/21/94     | PCT   |           |             |               |                  |
|             | B8              | WO 93/10220  | 05/27/93     | PCT   |           | 11/18/92    |               | Y                |
|             | B9              | 0 393 707 A2 | 10/24/90     | EP    |           | 04/20/90    |               | Y                |

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| <b>EXAMINER</b> | <b>DATE CONSIDERED</b> |
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FORM PTO - 1449

INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: HAR-005

APPLICANT(S): Wucherpennig et al.

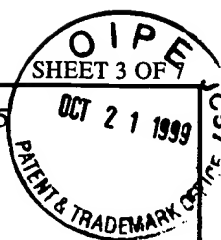
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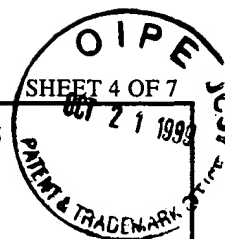
FILING DATE: February 12, 1999 GROUP: 1646

OTHER ART, JOURNAL ARTICLES, ETC.

| EXAM.<br>INIT. | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) |  |
|----------------|--|--|
|                | C1   | Altman <i>et al.</i> , "Phenotypic Analysis of Antigen-Specific T Lymphocytes" <i>Science</i> , 274:94-96 (1996)   |
|                | C2   | Angel <i>et al.</i> , "Oncogene <i>jun</i> encodes a sequence-specific <i>trans</i> -activator similar to AP-1," <i>Nature</i> , 332:166-171 (1988)  |
|                | C3   | Avva <i>et al.</i> , "In Vivo and In Vitro Formation and Dissociation of HLA-DR Complexes with Invariant Chain-Derived Peptides," <i>Immunity</i> , 1:763-774 (1994)   |
|                | C4   | Bell, T.W., "Molecular Trees: A New Branch of Chemistry," <i>Science</i> , 271(5252):1077-8 (1996)   |
|                | C5   | Bodmer <i>et al.</i> , "Nomenclature for factors of the HLA system, 1995," <i>Tissue Antigens</i> , 46:1-18 (1995)   |
|                | C6   | Borman, S., "Technique gets peptides into living cells," <i>C&amp;EN</i> , 27-28 (July 10, 1995)   |
|                | C7   | Bradley, D., "Dendrimers Display Liquid Crystal Talents," <i>Science</i> , 270:22 (1995)   |
|                | C8   | Brake, A.J., Alpha-Factor Leader-Directed Secretion of Heterologous Proteins from Yeast," <i>Methods in Enzymology</i> , 185:408-421 (1990)  |
|                | C9   | Brown <i>et al.</i> , "Three-dimensional structure of the human class II histocompatibility antigen HLA-DR1," <i>Nature</i> , 364:33-39 (1993)   |
|                | C10  | Chan <i>et al.</i> , "Cloning and bacterial expression of a secreted soluble human MHC Class II beta-1 domain," <i>Biochemical Society Transactions</i> , 20:322S (1992)   |
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|                | C12  | Chicz <i>et al.</i> , "Self-peptides bound to the type I diabetes associated class II MHC molecules HLA-DQ1 and HLA-DQ8," <i>International Immunology</i> , 6(11):1639-1649 (1994)   |
|                | C13  | Chicz <i>et al.</i> , "Specificity and Promiscuity among Naturally Processed peptides Bound to HLA-DR Alleles," <i>J. Exp. Med.</i> , 178:27-47 (1993)   |
|                | C14  | Claus <i>et al.</i> , "Are soluble monocyte-derived HLA class II molecules candidates for immunosuppressive activity?," <i>Immunology Letters</i> , 26(3):203-210 (1990)   |
| EXAMINER       |  | DATE CONSIDERED  |

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| <b>FORM PTO - 1449</b><br><br><b>INFORMATION DISCLOSURE STATEMENT</b> |   | ATTORNEY DOCKET NO.: HAR-005<br><br>APPLICANT(S): Wucherpfennig et al.<br><br>SERIAL NO.: 09/248,964<br><br>FILING DATE: February 12, 1999      GROUP: 1646  |  |
| <b>OTHER ART, JOURNAL ARTICLES, ETC.</b>                              |   |  |  |
| <b>EXAM.<br/>INIT.</b>  | <b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b> |  |  |
|   | C15   | Collins <i>et al.</i> , "The three-dimensional structure of a class I major histocompatibility complex molecule missing the $\alpha 3$ domain of the heavy chain," <i>Proc. Natl. Acad. Sci. USA</i> , 92:1218-1221 (1995) |  |
|   | C16   | Cosson <i>et al.</i> , "Role of Transmembrane Domain Interactions in the assembly of Class II MHC Molecules" <i>Science</i> , 258:659-662 (1992)   |  |
|   | C17   | Cregg <i>et al.</i> , "High-Level Expression and Efficient Assembly of Hepatitis B Surface Antigen in the Methylophilic Yeast, <i>Pichia Pastoris</i> ," <i>Bio/Technology</i> , 5:479-485 (1987)                          |  |
|   | C18   | Dagani, R., "Chemists Explore Potential of Dendritic Macromolecules as Functional Materials," <i>C&amp;EN</i> , 30-38 (June 3, 1996)   |  |
|   | C19   | DeSimone, J.M., "Branching Out into New Polymer Markets," <i>Science</i> , 269:1060-1062 (1995)  |  |
|   | C20   | Ferré-D'Amaré <i>et al.</i> , "Recognition by Max of its cognate DNA through a dimeric b/HLH/Z domain," <i>Nature</i> , 363:38-45 (1993)   |  |
|   | C21   | Fréchet, J.M.J., "Functional Polymers and Dendrimers: Reactivity, Molecular Architecture, and Interfacial Energy," <i>Science</i> , 263:1710-1715 (1994)   |  |
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|   | C23   | Freemantle, M., "Potential Trigger for Dendrimer Switch," <i>C&amp;EN</i> , p. 30 (May 26, 1997)   |  |
|   | C24   | Galliot, C., "Regioselective Stepwise Growth of Dendrimer Units in the Internal Voids of a Main Dendrimer," <i>Science</i> , 277:1981-1984 (1997)  |  |
|   | C25   | Grégoire <i>et al.</i> , "Engineered secreted T-cell receptor $\alpha\beta$ heterodimers," <i>Proc. Natl. Acad. Sci. USA</i> , 88:8077-8081 (1991)   |  |
|   | C26   | Hammer <i>et al.</i> , "Analysis of MHC Class II Peptide Interaction with M13 Peptide Display Libraries," <i>The Journal of Cellular Biochemistry</i> , Suppl. 17C, p. 215 (1993)  |  |
|   | C27   | Hu <i>et al.</i> , "Sequence Requirements for Coiled-Coils: Analysis with $\lambda$ Repressor-GCN4 Leucine Zipper Fusions," <i>Science</i> , 250:1400-1403 (1990)  |  |
|   | C28   | Hudson <i>et al.</i> , "Direct Visualization of Individual Cylindrical and Spherical Supramolecular Dendrimers," <i>Science</i> , 278:449-452 (1997)   |  |
| <b>EXAMINER</b>   |   | <b>DATE CONSIDERED</b>   |  |



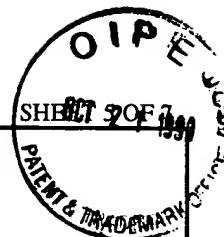


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| <b>FORM PTO - 1449</b><br><br><b>INFORMATION DISCLOSURE STATEMENT</b> | <b>ATTORNEY DOCKET NO.:</b> HAR-005                      |
|   | <b>APPLICANT(S):</b> Wucherpfennig et al.                |
|   | <b>SERIAL NO.:</b> 09/248,964                            |
|   | <b>FILING DATE:</b> February 12, 1999 <b>GROUP:</b> 1646 |

**OTHER ART, JOURNAL ARTICLES, ETC.**

| EXAM. INIT.     | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) |   |
|-----------------|--|---|
|                 | C29  | Jansen <i>et al.</i> , "Encapsulation of Guest Molecules into a Dendritic Box," <i>Science</i> , 266:1226-1230 (1994)   |
|                 | C30  | Jiang <i>et al.</i> , "Photoisomerization in dendrimers by harvesting of low-energy photons," <i>Nature</i> , 388(31):454-456 (1997)  |
|                 | C31  | Jones, E.V., "MHC class I and class II structures," <i>Curr. Opin. Immunol.</i> , 9(1):75-79 (1997)   |
|                 | C32  | Kalandadze <i>et al.</i> , "Expression of Recombinant HLA-DR2 Molecules," <i>The Journal of Biological Chemistry</i> , 271(33):20156-20162 (1996)   |
|                 | C33  | Kozono <i>et al.</i> , "Production of soluble MHC class II proteins with covalently bound single peptides," <i>Letters to Nature</i> , 369:151-154 (1994)   |
|                 | C34  | Kwok <i>et al.</i> , "Allele-Specific Motifs Characterize HLA-DLQ Interactions with a Diabetes-Associated Peptide Derived from Glutamic Acid Decarboxylase," <i>The Journal of Immunology</i> , 156(6):2171-2177 (1996)   |
|                 | C35  | Kwok <i>et al.</i> , "HLA-DQB1 Codon 57 is Critical for Peptide Binding and Recognition," <i>Journal of Experimental Medicine</i> , 183(3):1253-1258 (1996)   |
|                 | C36  | Heard, R., "HLA and autoimmune disease," <i>HLA and Disease</i> , 1994 Academic Press Ltd. pp. 123-151  |
|                 | C37  | Lin <i>et al.</i> , "Inhibition of Nuclear Translocation of Transcription Factor NF- $\kappa$ B by a Synthetic Peptide Containing a Cell Membrane-permeable Motif and Nuclear Localization Sequence," <i>The Journal of Biological Chemistry</i> , 270(24):14255-14258 (1995) |
|                 | C38  | Madden, D.R., "The Three-Dimensional Structure of Peptide-MHC Complexes," <i>Annu. Rev. Immunol.</i> , 13:587-622 (1995)  |
|                 | C39  | Marsh <i>et al.</i> , "HLA Class II region nucleotide sequences, 1995," <i>Tissue Antigens</i> , 45:258-280 (1995)  |
|                 | C40  | Marsh, S.G.E., "Nomenclature for factors of the HLA system, update June 1995," <i>Tissue Antigens</i> , 46:142-143 (1995)   |
|                 | C41  | Mottershead <i>et al.</i> , "Direct Binding of the Mtv7 superantigen (Mls-1) to Soluble MHC Class II Molecules," <i>Immunity</i> , 2:149-154 (1995)   |
|                 | C42  | Nag <i>et al.</i> , "Functionally Active Recombinant and Chain-Peptide Complexes of Human Major Histocompatibility Class II Molecules" <i>The Journal of Biological Chemistry</i> , 271(17): 10413-10417 (1996)   |
| <b>EXAMINER</b> |  | <b>DATE CONSIDERED</b>  |





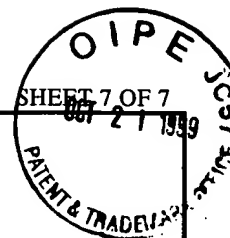
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| <b>FORM PTO - 1449</b><br><br><b>INFORMATION DISCLOSURE STATEMENT</b> | <b>ATTORNEY DOCKET NO.:</b> HAR-005<br><br><b>APPLICANT(S):</b> Wucherpfennig et al.<br><br><b>SERIAL NO.:</b> 09/248,964<br><br><b>FILING DATE:</b> February 12, 1999 <b>GROUP:</b> 1646 |
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| <b>OTHER ART, JOURNAL ARTICLES, ETC.</b> |
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| EXAM. INIT.     | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) |  |
|-----------------|--|--|
|                 | C43  | Nag <i>et al.</i> , "In Vitro Maximum Binding of Antigenic Peptides to Murine MHC Class II Molecules does not Always Take Place at the Acidic pH of the In Vivo Endosomal Compartment," <i>The Journal of Immunology</i> , 148(2):369-372 (1992)                           |
|                 | C44  | Nicolle <i>et al.</i> , "Specific Tolerance to an Acetylcholine Receptor Epitope Induced in Vitro in Myasthenia Gravis CD4 <sup>+</sup> Lymphocytes by Soluble Major Histocompatibility Complex Class II-Peptide Complexes," <i>J. Clin. Invest.</i> , 93:1361-1369 (1994) |
|                 | C45  | Ohnishi, K., "Domain Structures and Molecular Evolution of Class I and Class II Major Histocompatibility Gene Complex (MHC) Products Deduced from Amino Acid and Nucleotide Sequence Homologies," <i>Origins of Life</i> , 14:707-715 (1984)                               |
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|                 | C47  | O'Shea <i>et al.</i> , "X-ray Structure of the GCN4 Leucine Zipper, a Two-stranded, Parallel Coiled Coil," <i>Science</i> , 254:539-544 (1991)   |
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| INFORMATION DISCLOSURE STATEMENT  |  | APPLICANT(S): Wucherpfennig et al.  |  |
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